

Application Number 10/825,965  
Responsive to Office Action mailed October 2, 2006

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### REMARKS

This Amendment is responsive to the Office Action dated October 2, 2006. Applicant has amended claims 1, 22, 47, and 77-79. Claims 1-6, 8-29, 31-49 and 69-82 remain pending.

#### Claim Rejections Under 35 U.S.C. § 103

The Office Action rejected claims 1, 2, 6, 8-19, 22-25, 29, 31-36, 38-44, 47-49, 69, 72-76 and 79-81 under 35 U.S.C. § 103(a) as being unpatentable over Sheldon et al. (US 6,449,508, hereinafter "Sheldon") in view of Stone et al. (US 6,102,874, hereinafter "Stone").

The Office Action also rejected claims 3, 26 and 82 under 35 U.S.C. § 103(a) as being unpatentable over Sheldon in view of Stone, and further in view of Thompson (US 5,233,984).

The Office Action also rejected claims 4, 5, 27, 28, 70, 71, 77 and 78 under 35 U.S.C. § 103(a) as being unpatentable over Sheldon in view of Stone et al. (US 6,102,874), and further in view of Bornzin et al. (US 5,514,162, hereinafter "Bornzin").

The Office Action also rejected claims 20, 21, 45 and 46 under 35 U.S.C. § 103(a) as being unpatentable over Sheldon in view of Stone, and further in view of McClure (US 6,659,968).

Applicant respectfully traverses these rejections to the extent such rejections may be considered applicable to the claims as amended. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed inventions.

Applicant has amended independent claims 1, 22, 47, and 77-79 to clarify that the claims require a method comprising associating each determined activity level with a therapy parameter set used by a medical device to deliver a therapy to the patient when the activity level was determined, that is, the therapy parameter set that was used at the time the activity level was determined. As described in Applicant's specification, associating a therapy parameter set with one or more activity levels determined while the therapy set was in use may allow a user to readily identify the therapy parameter sets that support the highest activity levels for the patient, and thus evaluate the relative efficacy of the parameter sets.<sup>1</sup> In other words, associating a therapy parameter set with one or more activity levels determined while the therapy set was in

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<sup>1</sup> Paragraph [0005].

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use may provide a user with an objective indication of the efficacy different sets of therapy parameters.<sup>2</sup>

In regard to independent claims 1, 22, 47, 77, 78, and 79, the Office Action cited Sheldon as a basis for rejection. However, Sheldon does not disclose associating each activity level with a therapy parameter set that was used by a medical device to deliver a therapy to a patient when the activity level was determined. Further, Sheldon does not disclose evaluation of therapy parameter sets used by a medical device to deliver a therapy to a patient based on patient activity levels gathered while the parameter sets were used.

Instead, Sheldon is directed to a device that provides closed-loop control of a cardiac pacing rate based on detected activity levels. Thus, in the Sheldon device, when an activity level is determined, it is not associated with the pacing rate that was in effect at the time the activity level is determined, and is instead used to determine a new pacing rate. Closed-loop control of a pacing rate as taught by Sheldon would not have motivated one ordinarily skilled in the art to associate activity level data with therapy parameter sets that were in use when the activity level was determined.

Furthermore, in regard to claims 1, 22, and 73, the Office Action noted that Sheldon fails to teach or suggest the determination of an average length of time that consecutively determined activity levels associated with the therapy parameter set were above the threshold. The Office Action argued that it would have been obvious to modify the Sheldon device to perform this function based on the teachings of Stone.

Applicant respectfully submits that the Examiner has misinterpreted the scope and content of Stone. Stone also fails to teach determining an average length of time that consecutively determined activity levels associated with the therapy parameter set were above the threshold. Instead, Stone teaches determining the number of active 1 minute periods in a 24 hour period.<sup>3</sup>

This is significantly different from determining an average length of time that consecutively determined activity levels associated with the therapy parameter set were above the threshold. Stone does not teach determining the average length of time that consecutively

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<sup>2</sup> Paragraph [0019].

<sup>3</sup> Stone, col. 14, ll. 34-48

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determined 1 minute periods were considered active, and instead merely teaches determining the total number of active minutes, whether or not they were consecutive. Accordingly, Stone provides no teaching that would overcome the identified deficiency of Sheldon with respect to the requirements of Applicant's claims 1, 22, and 73.

In regard to claims 3, 26, and 82, the Office Action stated that Thompson teaches activity sensors that give an indication of whether a patient is at rest or active, and argued that it would have been obvious to include this feature in the Sheldon device simply because it is taught by Thompson. This argument fails to support a conclusion that claims 3, 26 and 82 are obvious for several reasons.

For example, claims 3, 26, and 8 require determining when a patient is awake and periodically determining an activity level while the patient is determined to be awake. Determining whether a patient is awake based on an activity sensor is not the same as determining activity levels while the patient is awake. Thus, whether or not Thompson teaches the former is irrelevant to the requirements of claims 3, 26, and 82.

Further, the Office Action has identified no teaching in the prior art of a motivation to combine the teaching of the applied references. The mere fact that a feature is taught in a secondary reference is not itself legally adequate to establish obviousness. A motivation to combine the secondary reference teaching with the primary reference teaching is also required.

Additionally, with respect to independent claims 47, 69 and 79, as well as dependent claims 13 and 36 the applied references fail to disclose or suggest presenting a list of the plurality of therapy parameter sets and activity metric values associated with the therapy parameter sets. The Office Action relied on Sheldon as teaching this feature. More particularly, the Office Action speculated that ranking activity counts as low, medium, or high, as taught by Sheldon, "could be implemented on a list."

This speculation is improper. There is no mention in Sheldon of presenting a list of parameter sets with associated designations as low, medium, or high. Nor would such a list be inherent in the Sheldon teachings. Neither Sheldon, nor any of the other references, discloses or suggests presenting a list of the plurality of therapy parameter sets and activity metric values associated with the therapy parameter sets.

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Further, the Office Action did not even address the requirements of claims 14, 15, 37, 38, 48, 49, 75, 76, 80 and 81. These claims recite ordering the list according to the activity metric, or a user selected one of a plurality of activity metrics. These requirements are also not taught in Sheldon, or the other references. Applicant respectfully requests that these claims be addressed or their rejection be withdrawn.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 1-6, 8-29, 31-49 and 69-82 under 35 U.S.C. § 103(a). Withdrawal of these rejections is requested.

**Rejection for Obviousness-type Double Patenting:**

The Office Action provisionally rejected claims 1-6, 8-29, 31-49 and 69-82 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of copending Application No. 11/106,051 and claims 1, 2 4-6, 9-13, 16-18, 20-22, 25-28, 30-32 and 35-37 of copending Application No. 11/081,873.

Applicant notes the provisional status of this rejection. Accordingly, Applicant will address this issue if and when the rejection is formally applied.

**CONCLUSION**

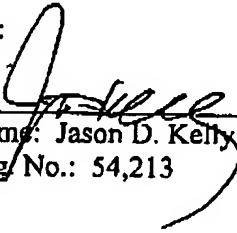
All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

1-3-07

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